

Food and Drug Administration College Park, MD

February 27, 2002

4202 "02 MAR -4 P1:34

Mr. Brooks Takenaka United Fishing Agency, Ltd. 117 Ahui Street Honolulu, HI 96813

Re: Docket No. 99D-0392

Dear Mr. Takenaka:

This letter is in response to your citizen petition dated August 24, 2001, which was received by the Food and Drug Administration (FDA) on August 29, 2001. You requested that the FDA use discretion relative to enforcement of some of the requirements of FDA's seafood Hazard Analysis Critical Control Point (HACCP) regulations (21 CFR Part 123) as provided under the agency's Seafood HACCP Transition Guidance of December 1999. Your petition asked the agency to accept one of your firm's HACCP approaches for controlling scombrotoxin in the fish processed at your firm until you complete studies to establish scientific validity of the approach.

In accordance with 21 CFR 10.30(e)(2), this letter is to advise you that we have not rendered a final decision on your petition within the first 180 days of its receipt. Per our recent discussions we will await your modification of the petition before responding.

Sincerely yours,

Philip £. Spiller

Director

Office of Seafood

Center for Food Safety and Applied Nutrition

cc.

GCF-1 (Kux)

HFA-305 (Docket No. 99D-0392)

HFC-1 (Baker)

HFR-PA100 (Linsley)

HFR-PA150 (Almogela)

HFS-1 (Levitt)

HFS-4 (Lake)

HFS-22 (Bailey)

HFS-24 (Brock)

HFS-400 (Spiller, Kraemer)

HFS-415 (Snyder)

HFS-416 (Hansen)

HFS-417 (Koonse, Samuels)

HFS-426 (Staruszkiewicz)

HFS-605 (Gushee)

f/t:HFS-417:RDSamuels:301-436-1418:2/27/02